

### Oregon Psilocybin Advisory Board



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# Equity Subcommittee

PAB Co-Chairs: Dr. Angela Carter, ND & Dr. Rachel Knox, MD, MBA

Meeting Notes: 06/04/2021

# Agenda

Attendance (5 min)

SC Updates: Licensing & Products (5 min)

Research Workshop (35 min)

Training Workshop (35 min)

Community Liaisons & Forums: Planning (20 min)

Public Comment (20 min)

# Licensing SC Update (5 min)

Brainstorming phase, identifying questions needing to be answered

- What type(s) of facilitator license(s) should be available?
- Client Bill of Rights + Responsibilities
  - Concerns around client refusal "for any reason"
- Facilitator Bill of Rights + Responsibilities
  - Facilitator screening

Upcoming discussion

- Informed consent

Centering Equity

- Address licensing & licensing process
- Establishing criteria around what it means to be an equity applicant in this space
  - Consider all indicators of overpoliced neighborhoods, e.g., underperforming schools
- Address past convictions/criminal records related to any drug use as a condition to deny licensure/participation and condition to prioritize
- Screen out mental health professionals with substantiated board complaints
- Ensure access/opportunity for businesses owned by marginalized communities (gender, sexual orientation, race, class, lived experiences, disabilities)
  - Create conditions for participation assurances, including space for representatives from marginalized communities and those with lived experiences to offer training and become facilitators, or supply chain operators

# **Licensing Discussion Continued**

#### Centering Equity (continued)

- Address affordability of applications, training, licensing fees, associated costs and long-term (unforeseen) costs to maintain and scale businesses (ask what is "affordable" and to "who"? And who is determining cost structures?)
  - $\succ$ Quantify costs of legal, consultant, etc.
  - Educate around "how to get in to the industry and  $\geq$ survive/thrive"; Avoid exclusively focusing on making the licensing process accessible
  - Identify what resources the state can provide, and  $\succ$ maintain resources through solvency and growth
- Ensure local opportunities, local/independent ownership, and protection of local market, ensuring space amongst well resourced biopharma/pharmaceutical company entry into the state market

### Needs:

- Appraisal of existing equity licensing models: pros/cons Learn from Cannabis SE experts/regulators  $\succ$
- Potential statutory changes for funding considerations to create resources to support equitable opportunity above taxes and fees (state fund, industry fund)
  - Short session '22 and long session '23)  $\succ$ 
    - One time and ongoing funding for an equity program
- Bold asks at the state and training programs and other entities around what we ask for and expect when implementing equity
  - Licensing fees waived for equity applicants  $\succ$
  - Require sliding scale  $\succ$
  - Require scholarships  $\succ$
  - Require a portion of licensing fees, taxes, and/or  $\succ$ percent of gross revenues to build an equity fund

# **Licensing Discussion Continued**

Centering Equity (continued)

- Pay attention to acculturation and its impact on consideration, inclusion, and prioritization of marginalized people (like immigrants)
- Address screening for professional conduct complaints
- Consider pre-licensing hurdles
  - Proper outreach to solicit interest in applying in the first place, communicating that all are wanted and welcome
  - > Who applies is a precursor to who gets licenses
- Ensure proper educational campaigns to communities that might benefit from services

### Needs (continued)

- Budgetary consideration for community outreach and education around enterprise opportunities
- Budgetary consideration for community outreach and education for people and communities that might benefit from services
- Hold listening forums of people (including those from marginalized communities) interested in applying for licensure
- Assess and stratify opportunity capacity across licensing types (to avoid saturation, oversupply, or bottlenecks) to grade access points to aid licensing considerations (e.g., there may be more capacity and thus opportunity in service centers than in cultivation)

# Products SC Update (5 min)

When and between whom are sales and taxes imparted?

What are the sources of psilocybin products? What species are allowed?

What are the equipment needs, best practices, and occupational hazards of each product pathway?

Tracking system considerations and data ownership? Blockchain considerations

Testing, speciation (major/minor compounds)

Dosing considerations, standardization; whole vs isolate, raw/fresh (wet) vs. dry

Cultivation, production, and preparation

Potential Speakers: Jim Keim, Daniel Ballhorn, Kyle Meyer, Paul Stamets, Felix Blei, Keith Williams, Benjamin Malcolm Centering Equity

- Address product (and service) costs; who is paying for product (service center/facilitator/client)?
- Address use of fees and tax funds and who/how they serve
- Create a mechanism to monitor industry/program economics
- Address capital needs to set up supply chain operations
- Necessity for diverse preparations (fresh to manufactured preparations, considering cost stratification as a barrier)
- Facility canopy/size restrictions
- PNW varieties (promote or protect?)
- Distribution/transportation logistics (minimize middle management and number of handoffs)
- Assess costs of analysis/testing and dose standardization
  - > Prioritize analysis over dose standardization
  - > Flexibility in dosing to accommodate whole fungi
- Avoid species and varietal limitations
- Consider subsidization for indoor facilities

# **Products Discussion Continued**

#### Centering Equity (continued)

- Consider that prohibiting outdoor cultivation not only creates a significant barrier to access through affordability, but is also not traditional and may sacrifice quality and benefit of truly natural grown fungi, making this an issue of equity and colonization
- Respect the difference between "psychedelic truffles" (sclerotia) vs. true truffles, and prohibit psychedelic truffles from being sold/marketed in PNW where there is a booming truffle market that's liable to be conflated
- Avoid too restrictive speciation limitations, recognizing the hard work of craft and cottage cultivators and the risk of boxing them/their product/their culture out of the industry in favor of what's "easy" for regulators

### Needs:

- Statute change to accommodate outdoor growing, which is not currently allowed under M109 which is limited to "indoor" under a "controlled environment"? What is a controlled environment?
  - Assurance of support for equitable access to capital, real estate, and equipment is a must
  - Consideration of a maximum facility/canopy size to prevent market monopolization and expand capacity around opportunity

# Research SC Update & Workshop (35 min)

### **Key Questions**

**KQ1**. What are the benefits and harms\* of psilocybin in controlled setting in persons seeking treatment for improving condition-specific symptoms and quality of life for:

a. Depression

b. Anxiety disorders

c. Trauma-related disorders, including racial trauma

d. Substance use disorders

e. Palliative care

f. Other conditions

KQ2. What are the benefits and harms\* of unsupervised psilocybin use?

KQ 1 & 2 Subquestion:

Sub question 1: How do the benefits and harms of psilocybin differ by population subgroups including but not limited to dosage, psilocybin source, age, setting, co-ingestion, or personal characteristics?

**KQ3**. What are provider or patient risk assessment tools that can identifying persons likely to benefit or be harmed by psilocybin-assisted therapy?

KQ4. What are the relative benefits and harms\* of different sources of psilocybin?

\*includes interpersonal, medical, and psychological harms

# **Research Workshop Continued**

### Questions/Feedback:

Replace "harms" with "risks" (harm is not inherent or inevitable), and "therapy" with "adult use" or "services" (therapy is an example of a type of use or type of service; not all services considered therapeutic)

- Risk assessment differentiation between highly regulated settings and more naturalistic, non-clinical settings with a broader cohort
- Differentiate data collection categories, e.g., "therapeutic,"
  "peer support", to distinguish "clinical/medical care" from
  "wellness"

Establish a collaborative process with the Equity SC to develop research reports and recommendations

#### Centering Equity: Additional key questions:

- What are ways of knowing and experiencing the world other than the western model?
- What are other ways of accumulating knowledge and information?
- Researching history how to acknowledge and report the natural history and traditional uses of psilocybin?
- What are research concepts coming from other cultures?
- For what purposes are diverse peoples and diverse cultures using psilocybin?
- How do we gather centuries' worth of experiential information, knowledge, and wisdom not documented in writing?
- How do we include all sources of information together (i.e., end evidence inequity)?
- What are ways to assess participatory research to ensure enough qualitate data to capture diversity of practices and outcomes that will emerge from the program?
  - How do we ensure that those participating in research own the data?
  - How do we maintain meaning to the diverse and local communities participating in this process.

# **Research Workshop Continued**

### Questions/Feedback:

Include a statement in the initial PAB research report to demonstrate acknowledgement and a commitment to sharing and edifying the initial report with answers to the "additional key questions"

Include a statement acknowledging the potential harm of stratifying "evidence" according to "high" and "low" quality, and RCT's designation as the "gold standard" of "high quality." All data is valuable in that they tell us different things

Collect anecdotal information from community; grassroots organizations can be helpful in obtaining stories based on real-world experiences that aren't reflected in RCTs

Collect wisdom information from spiritual/religious organizations aligned with historical and traditional use

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# Training SC Update & Workshop (35 min)

Training SC members will have speaker series over the next several weeks

Suggested speakers: Allan Davis, Rosalyn Watts, Francoise Bourzat, Hanna McLain, Brian Anderson, Claudia Cuentas, Pilar Hernandez-Wolfe

Proposed timeline:

July 1: 1st draft

July 15: Second draft

Sept 1: PAB approval of recommendations

Oct 1: OHA publishes draft rules

Nov 15: OHA adopts recommendations

Jan 1, 2022: OHA begins taking applications

Feb 1: 1st round of facilitators begin training

Jan 2, 2023: 1st licenses issued

# **Training Workshop Continued**

### Questions/Feedback:

Look at contraindications through a holistically inclusive lens to ensure that we don't wrongfully exclude already marginalized groups

When exploring what the risk assessment will look like, ask "who will be inherently included/excluded, and how can we make the framework as culturally competent as possible?"

Ensure inclusive cultural elements in service settings

Avoid assigning the designation of "harm" to experiences of anxiety or dissociation that may be an essential pathway for therapeutic progress;

- How do we look at adverse outcomes? Difficult will come up and difficult is not inherently bad.
- How do we study and track this? What information should be collected?
- How can we design a screening flanked by pre- and post-research to improve program as it matures?

#### Centering Equity

- Create conditions for participation assurances, including space for marginalized communities to offer training and become facilitators
- Establish peer support network consisting of those with life experience with mental illness
- Address affordability and accessibility of training programs

# Community Liaisons & Forums

Who do we want to hear from?

How do we create the forum for listening?

How do we compile the information we gather?

# Public Comment (20 minutes)

Recommendations from the public:

- Expand considerations for licensure beyond conviction to allowing applicants to submit relevant parts of the discovery of the case wherein a conviction may be the result of a plea bargain to a "seemingly" unrelated offense
- Re: equitable access for cultivators/manufacturers, establish a centralized entity (academic or private non-profit) to serve as an IP (common to novelty) bank
- Unique considerations for DNA based data/information to identify and trace products (e.g., follow isolates through lineages, through change of hands, and across time